IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

DANCIS EENWICK at al

FRANCIS FENWICK et al.,

Civil Action No.: 12-7354 (PGS)(DEA)

Plaintiffs,

:

v.

RANBAXY PHARMACEUTICALS INC. et al.,

:

Defendants.

rejenaanis.

<u>DEFENDANTS' ANSWER TO PLAINTIFFS' THIRD AMENDED</u> <u>CLASS ACTION COMPLAINT AND JURY DEMAND</u>

Defendants Ranbaxy Pharmaceuticals Inc., Ranbaxy Laboratories, Ltd., Ranbaxy Laboratories, Inc. Ranbaxy, Inc., Ranbaxy USA, and Ohm Laboratories (collectively, "Defendants") answer the allegations in Plaintiffs' Third Amended Complaint as follows:

- 1. Defendants deny the allegations in paragraph 1 except admit that (1) Plaintiffs purport to bring this action on behalf of all persons in the United States who purchased certain bottles of Defendants' Atorvastatin product, which is a generic version of Lipitor and that in or before November 2012, Defendants discovered the potential that some of the product contained small glass particles the size of grains of sand.
- 2. Defendants admit the first sentence of paragraph 2, except deny that the product was "adulterated." Defendants deny the remaining allegations of paragraph 2 except admit that Defendants have not offered a refund or replacement product to consumers who purchased product that came from the recalled lots.
 - 3. Defendants deny the allegations of paragraph 3.
 - 4. Defendants deny the allegations of paragraph 4, including subparts (a) through (j)

except admit that Plaintiffs seek the relief described therein.

JURISDICTION AND VENUE

- 5. Defendants lack information sufficient to form a belief as to the truth of the allegations in paragraph 5.
- 6. Defendants lack information sufficient to form a belief as to the truth of the allegations in the second sentence of paragraph 6. Defendants admit that they receive compensation from the sale of the product in New Jersey and that certain of the Defendants have offices in New Jersey. The remainder of paragraph 6 states legal conclusions to which no response is required.
 - 7. Paragraph 7 states a legal conclusion to which no response is required.

PARTIES

- 8. Defendants lack information sufficient to form a belief as to the truth of the allegations in paragraph 8.
- 9. Defendants lack information sufficient to form a belief as to the truth of the allegations in paragraph 9.
- 10. Defendants lack information sufficient to form a belief as to the truth of the allegations in paragraph 10.
- 11. Defendants lack information sufficient to form a belief as to the truth of the allegations in paragraph 11.
- 12. Defendants lack information sufficient to form a belief as to the truth of the allegations in paragraph 12.
- 13. Defendants admit the allegations in paragraph 13, except to state that (a) Ranbaxy Laboratories Limited consummated a merger with Sun Pharmaceutical Industries Limited ("SPIL") as of March 24, 2015, and that the combined entity is now known as "Sun

Pharmaceuticals Industries Limited," and (b) Ranbaxy USA, Inc. was dissolved as of October 24, 2014.

- 14. Defendants deny the allegations in paragraph 14 and state that Sun Pharmaceutical Industries Limited is the indirect parent of Ranbaxy, Inc.
- 15. Defendants admit the allegations in paragraph 15, except state that Ranbaxy USA, Inc. was dissolved as of October 24, 2014, and deny that Ranbaxy, Inc. was incorporated on the date indicated in paragraph 15.
 - 16. Defendants admit the allegations in paragraph 16.
 - 17. Defendants admit the allegations in paragraph 17.
- 18. Defendants deny the allegations in paragraph 18 the first sentence of paragraph18. Defendants admit the allegations in the second sentence of paragraph 18.
 - 19. Defendants admit the allegations in paragraph 19.
 - 20. Defendants admit the allegations in paragraph 20.
 - 21. Defendants admit the allegations in the first sentence of paragraph 21.

Defendants do not understand the second sentence and therefore deny the allegations in that sentence.

- 22. Defendants deny the allegations in paragraph 22.
- 23. Defendants lack information sufficient to form a belief as to the truth of the allegations in paragraph 23.
- 24. Defendants lack information sufficient to form a belief as to the truth of the allegations in paragraph 24.
- 25. Defendants lack information sufficient to form a belief as to the truth of the allegations in paragraph 25.

- 26. Defendants lack information sufficient to form a belief as to the truth of the allegations in paragraph 26.
- 27. Defendants lack information sufficient to form a belief as to the truth of the allegations in paragraph 27.
- 28. Defendants deny the allegations in paragraph 28 except admit that Defendants conducted a voluntary recall of certain lots of the product at a retail level and that Defendants maintained a website that included the lot numbers that had been part of the voluntary recall. Defendants also refer to the text of the Wall Street Journal article and deny any allegations inconsistent therewith.
- 29. Defendants deny the allegations in paragraph 29 except admit that Defendants conducted a voluntary recall at the retail level and have not offered a refund or replacement product to consumers who purchased product that came from the recalled lots.
 - 30. Defendants deny the allegations in paragraph 30.
- 31. Defendants lack information sufficient to form a belief as to the truth of the allegations in paragraph 31.
- 32. Defendants deny the allegations in paragraph 32 except admit that Defendants conducted a voluntary recall at the retail level and have not offered a refund or replacement product to consumers who purchased product that came from the recalled lots.
- 33. Defendants refer to the complete text of the website quoted in paragraph 33 and deny any allegations inconsistent therewith.
- 34. Defendants deny the allegations in paragraph 34 except admit that Defendants have not offered a refund or replacement product to consumers who purchased product that came from the recalled lots.

- 35. Defendants lack information sufficient to form a belief as to the truth of the allegations in paragraph 35 except admit that Defendants have not offered a refund or replacement product to consumers who purchased product that came from the recalled lots.
- 36. Defendants lack information sufficient to form a belief as to the truth of the allegations in paragraph 36. Defendants are unaware of the source of the "claim" or what "FDA Guidelines" are referenced in that paragraph.
 - 37. Defendants deny the allegations in paragraph 37.
 - 38. Defendants deny the allegations in paragraph 38.

CLASS ACTION ALLEGATIONS

Class Definition.

- 39. Defendants deny the allegations in paragraph 39 except admit that Plaintiffs purport to file this case as a class action.
 - 40. Defendants deny the allegations in paragraph 40.

Impracticable Joinder.

41. Defendants deny the allegations in paragraph 41.

Risk of Inconsistent or Varying Adjudications.

- 42. Defendants deny the allegations in paragraph 42.
- 43. Defendants deny the allegations in paragraph 43.
- 44. Defendants deny the allegations in paragraph 44.

Common Questions of Law and Fact.

45. Defendants deny the allegations in paragraph 45 and subparts (a) through (f).

Typicality.

46. Defendants deny the allegations in paragraph 46.

Fair and Adequate Representation.

47. Defendants deny the allegations in paragraph 47.

Superiority of Class Action Procedure.

- 48. Defendants deny the allegations in paragraph 48.
- 49. Defendants deny the allegations in paragraph 49.
- 50. Defendants deny the allegations in paragraph 50.

CLAIMS

51. Defendants deny the allegations in paragraph 51.

COUNT ONE BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

- 52. Defendants repeat and reincorporate their answers to paragraphs 1-51.
- 53. Defendants admit the allegations of paragraph 53.
- 54. Defendants admit the allegations of paragraph 54.
- 55. Defendants deny the allegations in paragraph 55.
- 56. Defendants deny the allegations in paragraph 56.
- 57. Defendants deny the allegations in paragraph 57.
- 58. Defendants deny the allegations in paragraph 58.
- 59. Defendants deny the allegations in paragraph 59.
- 60. Defendants deny the allegations in paragraph 60.

COUNT TWO UCC ARTICLE 2-314 IMPLIED WARRANTY OF MERCHANTABILITY

- 61. Defendants repeat and reincorporate their answers to paragraphs 1-60.
- 62. Paragraph 62 states a legal conclusion to which no response is required.
- 63. Paragraph 63 states a legal conclusion to which no response is required.

- 64. Paragraph 64 states a legal conclusion to which no response is required.
- 65. Defendants admit the allegations in paragraph 65.
- 66. Defendants deny the allegations in paragraph 66.
- 67. Defendants deny the allegations in paragraph 67.
- 68. Defendants deny the allegations in paragraph 68.
- 69. Defendants deny the allegations in paragraph 69.
- 70. Defendants deny the allegations in paragraph 70.
- 71. Defendants deny the allegations in paragraph 71.

COUNT THREE BREACH OF EXPRESS WARRANTY

- 72. Defendants repeat and reincorporate their answers to paragraphs 1-71.
- 73. Defendants admit the allegations in paragraph 73.
- 74. Defendants admit the allegations in paragraph 74.
- 75. Defendants deny the allegations in paragraph 75.
- 76. Defendants deny the allegations in paragraph 76.
- 77. Defendants deny the allegations in paragraph 77.
- 78. Defendants deny the allegations in paragraph 78.
- 79. Defendants deny the allegations in paragraph 79.

COUNT FOUR UCC ARTICLE 2-313 EXPRESS WARRANTY

- 80. Defendants repeat and reincorporate their answers to paragraphs 1-79.
- 81. Paragraph 81 states a legal conclusion to which no response is required.
- 82. Paragraph 82 states a legal conclusion to which no response is required.
- 83. Paragraph 83 states a legal conclusion to which no response is required.

- 84. Defendants admit the allegations in paragraph 84.
- 85. Defendants admit the allegations in paragraph 85.
- 86. Defendants deny the allegations in paragraph 86.
- 87. Defendants deny the allegations in paragraph 87.
- 88. Defendants deny the allegations in paragraph 88.
- 89. Defendants deny the allegations in paragraph 89.
- 90. Defendants deny the allegations in paragraph 90.

COUNT FIVE UNJUST ENRICHMENT

- 91. Defendants repeat and reincorporate their answers to paragraphs 1-90.
- 92. Defendants deny the allegations in paragraph 92.
- 93. Defendants deny the allegations in paragraph 93.

PRAYER FOR RELIEF

Defendants deny that Plaintiffs are entitled to any of the relief sought.

AFFIRMATIVE DEFENSES

Defendants do not assume the burden of proof on any of the following affirmative defenses where the substantive law provides otherwise.

- 1. Plaintiffs fail to state a claim upon which relief can be granted.
- 2. Plaintiffs' claims are barred, in whole or in part, because Plaintiffs have not suffered any damages or injury from any act of Defendants.
- 3. Plaintiffs' claims are barred, in whole or in part, because Plaintiffs and the putative class lack standing to assert their claims.
- 4. Plaintiffs' claims are not properly maintainable as a class action.
- 5. Plaintiffs' claims are preempted by federal laws, regulations and decisions of the FDA.
- 6. Plaintiffs' claims are foreclosed by the FDA's primary jurisdiction over the matter.

- 7. Plaintiffs' claims are barred because any acts taken by Defendants were in compliance with applicable statutes and regulations.
- 8. Plaintiffs' claims are barred, in whole or in part, by the doctrines of waiver, estoppel, unclean hands and/or laches.
- 9. Plaintiffs' claims are barred in whole or in part by the New Jersey Products Liability Act.
- 10. Defendants reserve all affirmative defenses under Federal Rule of Civil Procedure 8(c) and any other defenses, at law or in equity, that may now exist or in the future be available based on discovery and further factual investigation in this case.

Dated: April 17, 2015 Respectfully submitted,

LITE DEPALMA GREENBERG, LLC

/s/ Michael E. Patunas

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CERTIFICATE OF SERVICE

I, Michael E. Patunas, hereby certify that on this day, I served a copy of Defendants' Answer to Plaintiffs' Third Amended Class Action Complaint and Jury Demand and Ranbaxy Defendants' Corporate Disclosure Statement on all counsel of record via the Court's ECF system.

April 17, 2015	/s/ Michael E. Patunas
-	Michael E. Patunas